NDA 21-226/S-001
NDA 21-251/S-001

Abbott Laboratories
Attention: Rebecca A. Welch
Associate Director, PPD Regulatory Affairs
100 Abbott Park Road
D-491, AP6B-1SW
Abbott Park, Illinois 60064-3500

JAN 30 2001

Dear Ms. Welch:

Please refer to your supplemental new drug applications dated December 27, 2000, received December 28, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for KALETRA®, 133.3/33.3 mg lopinavir/ritonavir capsules and 80/20 mg lopinavir/ritonavir oral solution.

We acknowledge receipt of your submission dated December 27, 2000.

These "Changes Being Effected" supplemental new drug applications provide for corrective changes to the Package Insert (PI) and Patient Package Insert (PPI) which include the following:

PI:

- Revisions to PRECAUTIONS section, Table 6 and ADVERSE REACTIONS section, Tables 7 and 8.
- Inclusion of a statement regarding dosing with a calibrated oral dosing syringe to the DOSAGE AND ADMINISTRATION: Pediatrics section.

PPI:

- Addition of information regarding Kaletra storage and breast feeding.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package insert submitted, December 27, 2000, patient package insert submitted, December 27, 2000). Accordingly, these supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Sean J. Belouin, R.Ph, Regulatory Project Manager, at 301-827-2335.

Sincerely,

Debra Birnkrant, M.D.
Acting Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research